DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
94888d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 3000202816

July 21, 2004

Jose A. Perez, Owner
Modesto Fish Company
5616 Swanson Road
Denair, California 95316

WARNING LETTER

Dear Mr. Perez:

On January 29 - 30, and February 2 - 6, 2004, the Food and Drug Administration (FDA) inspected your seafood processing facility, Modesto Fish Company, located at 5616 Swanson Road, Denair, California, and found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations Part 123 (21 CFR 123) Fish and Fishery Products. At the conclusion of the inspection, you were issued a Form FDA 483 on which these deviations were listed and then they were discussed with you. A copy of that Form FDA 483 is enclosed for your reference.

In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated

- Histamine forming fish, specifically Mahi Mahi, and
- Ready-to-eat cooked crab

are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov. Attached is a handout describing how to obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

The serious HACCP deviations noted at your Denair, California facility and through review of the written Establishment Inspection Report (EIR), which was prepared based on the current inspection, were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for Mahi Mahi to control the food safety hazard of histamine formation as a result of time/temperature abuse.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for Cooked Crab does not list the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse.

You must immediately take appropriate steps to correct the violations. If you do not promptly correct these violations, we may take further action, for instance, we may seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the revised HACCP plan, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the current Good Manufacturing Practices (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Barbara J. Cassens
District Director
San Francisco District

Enclosures

Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

Form FDA 483